

2007-02-06 06:00:00 PCT-1990 (Rev. 07-2005)  
Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|   |  |  |
|---|--|--|
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | ATTORNEY'S DOCKET NUMBER<br>2000301.126US1                   |
| INTERNATIONAL APPLICATION NO.<br>PCT/GB2003/003322  | INTERNATIONAL FILING DATE<br>July 31, 2003 | U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br>10/523462 |
|   |  | PRIORITY DATE CLAIMED<br>August 3, 2002                      |
| <b>TITLE OF INVENTION</b><br><b>ANALYSIS OF BIOLOGICAL SAMPLES</b><br><b>APPLICANT(S) FOR DO/EO/US</b><br>Gerard Brady  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |
| 1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.<br>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.<br>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input type="checkbox"/> The US has been elected (Article 31).<br>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))<br>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> has been communicated by the International Bureau.<br>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).<br>a. <input type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).<br><b>Items 11 to 20 below concern document(s) or information included:</b><br>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.<br>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.<br>13. <input type="checkbox"/> A preliminary amendment.<br>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.<br>15. <input type="checkbox"/> A substitute specification.<br>16. <input type="checkbox"/> A power of attorney and/or change of address letter.<br>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.<br>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). |  |  |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|   |              |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
|---|--------------|---|--|---|-------|--|-------------|--|-------|----|-------|----------------------------|-------|----|--|--|
| U. S. APPLICATION NO. (if known, see 37 CFR 1.5)<br>10/523462   |              | INTERNATIONAL APPLICATION NO.   | ATTORNEY'S DOCKET NUMBER<br>2000301.126US1 |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>20. <input checked="" type="checkbox"/> Other items or information:</p> <ul style="list-style-type: none"> <li>- Paper copy of Sequence Listing</li> <li>- Statement</li> <li>- Amendment</li> <li>- Copy of Notice to Comply</li> <li>- Return Receipt Postcard</li> </ul>  |              |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>The following fees have been submitted</p> <table border="1"> <tr> <td>21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....</td> <td>\$300</td> <td>CALCULATIONS</td> <td>PTO USEONLY</td> </tr> <tr> <td>22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))<br/>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....</td> <td>\$0</td> <td>\$</td> <td></td> </tr> <tr> <td>All other situations .....</td> <td>\$200</td> <td>\$</td> <td></td> </tr> </table>  |              |   |  | 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....   | \$300 | CALCULATIONS   | PTO USEONLY | 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))<br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... | \$0   | \$ |       | All other situations ..... | \$200 | \$ |  |  |
| 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....   | \$300        | CALCULATIONS  | PTO USEONLY                                |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))<br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....  | \$0          | \$  |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| All other situations .....  | \$200        | \$  |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))<br/>If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....</p> <table border="1"> <tr> <td>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....</td> <td>\$0</td> </tr> <tr> <td>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....</td> <td>\$100</td> </tr> <tr> <td>All other situations .....</td> <td>\$400</td> </tr> <tr> <td></td> <td>\$500</td> </tr> </table> |              |   |  | Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... | \$0   | International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... | \$100       | All other situations .....   | \$400 |    | \$500 |                            |       |    |  |  |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....   | \$0          |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....  | \$100        |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| All other situations .....  | \$400        |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
|   | \$500        |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><b>TOTAL OF 21, 22 and 23 =</b></p>  |              |   |  | \$ 0.00   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br/>The fee is \$250 for each additional 50 sheets of paper or fraction thereof.</p>   |              |   |  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| Total Sheets  | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE                                       |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| - 100 =   | /50 =        |   | x \$250.00                                 | \$  |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).</p>   |              |   |  | \$  |       |  |             |  |       |    |       |                            |       |    |  |  |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA  | RATE                                       |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| Total claims  | - 20 =       |   | x  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| Independent claims  | - 3 =        |   | x  |   |       |  |             |  |       |    |       |                            |       |    |  |  |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |   |  | +   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><b>TOTAL OF ABOVE CALCULATIONS =</b></p>   |              |   |  | \$ 0.00   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.</p>  |              |   |  | 0.00  |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><b>SUBTOTAL =</b></p>  |              |   |  | \$ 0.00   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</p>  |              |   |  | \$  |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><b>TOTAL NATIONAL FEE =</b></p>  |              |   |  | \$ 0.00   |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p>Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property</p>   |              |   |  | \$  |       |  |             |  |       |    |       |                            |       |    |  |  |
|   |              |   |  | \$  |       |  |             |  |       |    |       |                            |       |    |  |  |
| <p><b>TOTAL FEES ENCLOSED =</b></p>   |              |   |  | \$ 0.00   |       |  |             |  |       |    |       |                            |       |    |  |  |
|   |              |   |  | Amount to be refunded: \$   |       |  |             |  |       |    |       |                            |       |    |  |  |
|   |              |   |  | Amount to be charged \$   |       |  |             |  |       |    |       |                            |       |    |  |  |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

a.  A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ 0.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.

c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-0219. A duplicate copy of this sheet is enclosed.

d.  Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.**

SEND ALL CORRESPONDENCE TO:

  
SIGNATURE

Michael J. Twomey

NAME

CUSTOMER NUMBER: 23483

38,349  
REGISTRATION NUMBER

Docket No.: 2000301.126US1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Gerard Brady

Application No.: 10/523462

Confirmation No.: 8249

Filed: February 1, 2005

Art Unit: 1645

For: ANALYSIS OF BIOLOGICAL SAMPLES

Examiner: Not Yet Assigned

Mail Stop PCT/DO/EO/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS  
FOR PATENT APPLICATION CONTAINING NUCLEOTIDE  
SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Dear Sir:

This is in response to the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, dated December 6, 2005. Applicants are submitting their response herewith within the two-month response period set to expire on February 6, 2006.

Enclosed for filing in the above-identified patent application are the following documents:

1. Diskette containing computer readable form of Sequence Listing;
2. Paper Copy of Sequence Listing;
3. Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§1.821-1.825;
4. Amendment;
5. Copy of Notice to Comply; and
6. Return Receipt Postcard.

In the event of a fee deficiency or an overpayment, kindly make the appropriate adjustment to Deposit Account No. 08-0219.

Dated: 6 February 2006

Respectfully submitted,

By Michael J. Twomey  
Michael J. Twomey  
Registration No.: 38,349  
WILMER CUTLER PICKERING HALE AND  
DORR LLP  
60 State Street  
Boston, Massachusetts 02109  
(617) 526-6000  
Attorney for Applicant



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

|  |                       |                  |
|--|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO.            | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/523,462                             | Gerard Brady          | 67890-3          |
| INTERNATIONAL APPLICATION NO.          |                       |                  |
| PCT/GB03/03322                         |                       |                  |
| I.A. FILING DATE                       | PRIORITY DATE         |                  |
| 07/31/2003                             | 08/03/2002            |                  |
| CONFIRMATION NO. 8249                  |                       |                  |
| 371 FORMALITIES LETTER                 |                       |                  |
| <br><small>*OC000000017591485*</small> |                       |                  |

Date Mailed: 12/06/2005

**NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS  
 CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice MUST be returned with the response.*

DONNA S GREENE

---

Telephone: (703) 308-9140 EXT 222

**PART 1 - ATTORNEY/APPLICANT COPY**

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/523,462                  | PCT/GB03/03322                | 67890-3          |

FORM PCT/DO/EO/922 (371 Formalities Notice)